



# V-safe COVID-19 Vaccine Pregnancy Registry

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#### Participation in the Registry

CDC invites people who received any dose of COVID-19 vaccine in the periconception period (within 30 days before last menstrual period) or during pregnancy to participate in the v-safe COVID-19 Vaccine Pregnancy Registry.

- Pregnant people who would like to participate must be enrolled in v-safe.
- If people enrolled in **v-safe** report that they were pregnant at the time of vaccination or became pregnant shortly after vaccination, the registry staff\* may call them to learn more about their pregnancy course and outcome.
- Even if you are no longer pregnant, you may still be eligible to enroll in the registry.

# V-safe and the V-safe COVID-19 Vaccine Pregnancy Registry: What's the Difference?

**v-safe** is a smartphone-based system that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine. The **v-safe** COVID-19 Vaccine Pregnancy Registry is for **v-safe** participants who self-identify as pregnant at the time of vaccination or shortly thereafter (within 30 days of vaccination). The registry activities are in addition to the **v-safe** after vaccination health check-ins that participants receive via text message.

# What to Expect If You Participate in the Registry

#### Phone Call Health Check-ins

Abt Associates . the registry staff contracted by CDC, will contact people by phone to invite them to participate in the registry.

People who choose to enroll in the registry will receive calls from Abt Associates several times throughout their pregnancy for additional health check-ins. During these check-ins, they will be asked questions about their pregnancy and medical history. After delivery, participants might be contacted for more information when their babies are about three months old.

## Requesting Permission to Contact Your Healthcare Provider

Participants will also be asked if they would be willing to provide permission for Pregnancy Registry staff to review their medical records for additional details about their pregnancies. Personal information and responses given to the registry are confidential and will be protected to the full extent allowed by law. Having information on details, like medications or clinical laboratory results, provides a complete picture of your pregnancy. Your healthcare provider(s) can help provide this information, which is important as we try to understand more about COVID-19 vaccination during pregnancy. If you choose not to give your permission for CDC to access medical records, you can still participate in the registry.

#### Participation Is Voluntary

Participants are not paid for their participation in the registry, and not all people reporting pregnancy will be contacted to participate. Participation is completely **voluntary**, and you can **opt out at any time.** However, in general, many people feel good about participating in activities to help answer critical scientific questions, which can help inform recommendations for the public.

## Registry Data Collection and Use

#### Who Is Participating in the Registry

CDC is currently enrolling eligible participants. As of May 2, 2022, the registry has enrolled 23,779 pregnant people in the United States.

#### Why CDC Is Collecting Registry Information

If you participate in the registry, the information you and other participants provide will be evaluated and used to educate the public about COVID-19 vaccines and pregnancy. In addition, this information will be used by CDC and the Food and Drug Administration (FDA) to guide recommendations on COVID-19 vaccination during pregnancy.

Specific health effects that scientists will be looking at include:

- Pregnancy outcomes, like miscarriage and stillbirth
- Pregnancy complications, like preeclampsia and gestational diabetes
- Problems with the newborn, like preterm delivery, poor growth, or birth defects

Data for the registry are kept on a CDC system that employs strict security measures to keep personally identifiable information private. Your name and any identifying information will not be included Information will be protected to the full extent allowed by law.

## How CDC Is Using Data from the Registry

In April 2021, CDC released the first U.S. data on the safety of mRNA COVID-19 vaccines administered during pregnancy based on analyses of data from three vaccine safety-related databases, including the **v-safe** COVID-19 Pregnancy Registry. The analyses did not identify any safety concerns for pregnant people who were vaccinated or for their babies. Additional follow-up is needed, particularly among those vaccinated in the first or second trimesters of pregnancy; however, these preliminary findings continue to indicate COVID-19 vaccines are safe and effective.

Data collected from the registry is also presented in published reports and at publicly open Advisory Committee on Immunization Practices (ACIP) meetings. However, gathering data on potential effects of COVID-19 vaccination during pregnancy is expected to take some time given the natural length of pregnancy. In addition, people are being vaccinated at different times during their pregnancies. CDC will share results as they are made available.

## Vaccine Safety Monitoring in People Who Are Breastfeeding

Based on how these vaccines build protection in the body, the authorized COVID-19 vaccines are not thought to be a risk to lactating people or their breastfeeding babies. Although the Pregnancy Registry does not look at COVID-19 vaccination and breastfeeding, other researchers across the nation are working to better understand COVID-19 vaccination and breastfeeding.

### Pregnacy Registry-Related Publications

- Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons
- Receipt of mRNA COVID-19 Vaccines and Risk of Spontaneous Abortion
- COVID-19 vaccine safety in pregnancy: Updates from the v-safe COVID-19 vaccine pregnancy registry <a>[</a> (ACIP

meeting slides)

- Updates on COVID-19 and Pregnancy (ACIP meeting slides)
- Monitoring the safety of COVID-19 vaccines in pregnancy in the U.S.

## How to Report Adverse Events

VAERS collects reports of possible adverse events that happen after vaccination. Anyone can submit a report to VAERS . including patients, parents or caregivers, healthcare providers, and vaccine manufacturers.

There are two ways to report an adverse event to VAERS: report online \( \text{\text{o}} \) or report using a writable pdf form \( \text{\text{c}} \) . If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

For healthcare providers – Under Emergency Use Authorization, FDA requires healthcare professionals to report to VAERS certain adverse events that occur after COVID-19 vaccination. CDC also encourages reporting of any medically important adverse event even if it isn't clear if the vaccine caused the health problem.

Learn more about selected adverse events reported to VAERS.

#### **Related Pages**

- COVID-19 Vaccine Safety and Monitoring
- > COVID-19 Vaccines While Pregnant or Breastfeeding
- > Benefits of Getting a COVID-19 Vaccine
- Myths and Facts about COVID-19 Vaccines
- > COVID Data Tracker: COVID-19 Vaccination Among Pregnant People

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